

Misbranding, Section 502 (a), the statements in the labeling of the article, "Soap U. S. P." and "Made from pure olive oil * * * The U. S. P.—100% pure olive oil soap," were false and misleading as applied to the article, which was not made from olive oil and which did not comply with the requirements of the Pharmacopoeia for alkali hydroxides, alkali carbonates, iodine value and solidifying point of the combined fatty acids, and the limit of saturated acids.

DISPOSITION: December 3, 1945. The New Brunswick Laboratories, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for repackaging and relabeling under the supervision of the Federal Security Agency.

1869. Adulteration and misbranding of gauze pads. U. S. v. 46 Boxes of Gauze Pads. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 17314. Sample No. 3645-H.)

LIBEL FILED: August 24, 1945, District of Maryland.

ALLEGED SHIPMENT: On or about June 15, 1945, by the Handy Pad Supply Co., from Worcester, Mass.

PRODUCT: 46 boxes of gauze pads at Baltimore, Md. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: (Boxes) "100 M-B Gauze Pads Absorbent Size 12"x18" Gauze Folded 3"x3" * * * Sterilized After Packaging."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Sterile Absorbent Gauze [Sterile Gauze]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (g), the article was not labeled as is prescribed in the Pharmacopoeia, since the type of gauze was not stated on the label.

DISPOSITION: November 16, 1945. The Handy Pad Supply Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond, conditioned that it be reesterilized and relabeled under the supervision of the Food and Drug Administration.

1870. Adulteration and misbranding of gauze. U. S. v. 150 Boxes and 400 Boxes of Gauze. Consent decrees of condemnation. Product ordered released under bond. (F. D. C. Nos. 17032, 17163. Sample Nos. 7217-H, 29086-H.)

LIBEL FILED: August 9 and 23, 1945, Northern District of New York and Northern District of California.

ALLEGED SHIPMENT: On or about May 4 and 11, 1945, by Allen Laboratories, Inc., from Palmer, Mass.

PRODUCT: 150 boxes and 400 boxes, each containing 500 units, of *gauze* at Binghamton, N. Y., and San Francisco, Calif., respectively.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Sterile Absorbent Gauze [Sterile Gauze]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: April 23 and May 17, 1946. Allen Laboratories, Inc., claimant, having consented to the entry of decrees, judgments of condemnation were entered and the product was ordered released under bond, conditioned that the unfit portion be segregated and reesterilized under the supervision of the Federal Security Agency.

1871. Adulteration and misbranding of prophylactics. U. S. v. 22 Gross and 47 Gross of Prophylactics. Default decrees of destruction. (F. D. C. Nos. 17551, 18052. Sample Nos. 18417-H, 47470-H.)

LIBELS FILED: October 27, 1945, and February 28, 1946, District of Minnesota and District of Utah.

ALLEGED SHIPMENT: On or about October 8, 1945, and January 7, 1946, by the Akron Drug and Sundries Co., from Akron, Ohio.

PRODUCT: 22 gross of *prophylactics* at Salt Lake City, Utah, and 47 gross of *Prophylactics* at Minneapolis, Minn. Examination of samples disclosed that 3.7 percent of those from the Minnesota lot and 7.9 percent of those from the Utah lot were defective in that they contained holes.

LABEL, IN PART: "Napoleons [or "Derbies"] Manufactured for Jay Dee Drug Co., Chicago, Ill., by the Killian Manufacturing Co., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement, "for prevention of disease," was false and misleading as applied to an article containing holes.

DISPOSITION: December 17, 1945, and April 5, 1946. No claimant having appeared, judgments were entered ordering that the product be destroyed.

1872. Adulteration and misbranding of prophylactics. U. S. v. 63½ Gross and 26½ Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 17517. Sample Nos. 23644-H, 23645-H.)

LABEL FILED: February 25, 1946, Southern District of Texas.

ALLEGED SHIPMENT: On or about June 24, 1945, by the World Merchandise Exchange, from New York, N. Y.

PRODUCT: 90 gross of *prophylactics* at Houston, Tex. Examination of samples indicated that 5 percent of the product was defective in that it contained holes.

LABEL, IN PART: "Lloyd's Made from Liquid Latex," and "Silver-Tex Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported to possess.

Misbranding, Section 502 (a), (portion) the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: April 11, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1873. Misbranding of sea water (Cal-O-Dine). U. S. v. 17 Bottles of Sea Water. Default decree of condemnation and destruction. (F. D. C. No. 17577. Sample No. 27976-H.)

LABEL FILED: October 4, 1945, District of Oregon.

ALLEGED SHIPMENT: From Alameda, Calif., by Cal-O-Dine. The product was shipped on or about June 22, 1945, and a number of leaflets were shipped on or about February 1, 1945.

PRODUCT: 17 ½-gallon bottles of sea water at Eugene, Oreg., together with a number of leaflets headed "The Mysterious ingredient of sea-water." Analyses indicated that the product was sea water.

LABEL, IN PART: "Sea Water Sold Under Trade Name of Cal-O-Dine."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "To supply trace minerals naturally occurring in sea water," was misleading since it represented and suggested that such trace minerals would have some nutritional or medicinal effect upon the user when the article was consumed in accordance with the directions upon the label, whereas those trace minerals would not have that effect, and the misleading effect of the statement was not corrected by the modifying phrase, "though in nutritionally non-significant amounts"; the label statement, "A difference in medical and nutritional opinion exists contrary to representations of value of this product. In favor of the value of trace minerals contained in sea water are the opinions of various medical and nutritional experts qualified by scientific training to evaluate," were false and misleading since there is no difference of opinion among qualified medical and nutritional experts with reference to the uselessness of sea water taken in accordance with the instructions specified on the label, either as a dietary supplement or as a remedial agent; and the entire labeling of the article was misleading in the absence of a statement of the fact, material in the light of the labeling, that the article would serve no useful purpose either as a nutritional adjuvant or as a drug when consumed in accordance with the directions on the label.

Further misbranding, Section 502 (a), the following statements in the leaflet, when read in connection with the label directions for ingestion of sea water,

*See also Nos. 1852, 1853, 1859, 1862, 1865-1868, 1870-1872.